Premarket Approval (PMA) Package for Dockets Management Branch

PMA Number P030023 Docket # 2004M-0248

Ophtec USA, Inc.
Oculaid™ Capsular Tension Ring (Model 275
10/12 mm and Model 276 11/13 mm) and
Stableyes™ Capsular Tension Ring (Model 275
10/12 mm and Model 276 11/13 mm)

Includes:

Approval Order
Summary of Safety and Effectiveness Data (SSED)
Labeling

AAV/